

## **REMARKS**

Reconsideration of the present application, as amended and in view of the following remarks, is respectfully requested. The application, as amended, includes claims 1, 2, 9-13, 30, 32, 33, 36-38, 42, 44-46, 55-63 and 66-67, pending and under consideration.

Applicant acknowledges and thanks the Examiner for the indication in the outstanding Office Action that claim 43 is allowed and that claims 12 and 46 would be allowable over the prior art if rewritten in independent form. The subject matter of prior claims 12 and 46 is now presented in new claims 66 and 67, in which the subject matter of prior claims 12 and 46 has been rewritten in independent form. It is believed that new claims 66 and 67 are in condition for allowance.

At the time the outstanding Office Action was mailed on September 23, 2005, claims 1-15, 30 and 32-65 were pending. Claims 3-8, 14, 34, 35, 39-41, 47-54, 64 and 65 have now been withdrawn from consideration, claim 43 is allowed, claims 12 and 46 are objected to as depending upon rejected base claims and claims 1, 2, 9-11, 13, 15, 30, 32, 33, 36-38, 42, 44, 45 and 55-63 stand rejected. For the reasons set forth below, Applicant submits that, and respectfully requests an indication that, each of pending claims 1, 2, 9-13, 30, 32, 33, 36-38, 42, 44-46, 55-63 and 66-67 is in condition for allowance.

### **Remarks Regarding Objection to the Specification**

In the outstanding Office Action, the specification is objected to under 37 CFR §1.75(d)(1). In making this objection, the Examiner states that, "The specification is

objected to as failing to provide proper antecedent basis for the claimed subject matter... Correction of the following is required: dumbbell.” Without acquiescing in this objection, Applicant submits that this objection is now moot in view of the above amendments, whereby the term “dumbbell” has been removed from claims 44 and 61. Application therefore respectfully submits that this objection has been overcome, and requests withdrawal of same.

**Remarks Regarding Information Disclosure Statement**

In the outstanding Office Action, the Examiner states that the information disclosure statement filed April 4, 2005 fails to comply with 37 CFR 1.98(a)(2) on the basis that no copies of publications and non-U.S. patents were submitted. While Applicant’s record indicates that such copies were sent with the April 4, 2005, Information Disclosure Statement, this point is now also mooted by the present submission of an information disclosure statement with which said copies are enclosed.

**Remarks Regarding Rejection of Claims Under 35 U.S.C. §102(b)**

In the outstanding Office Action, claims 1-2, 10, 15-16 and 57-58 are rejected under 35 U.S.C. §102(b), as being anticipated by Grosse et al. (WO 97/23174). In support of this rejection, the Action states in part that, “Referring to figure 14, the end pieces are interpreted as being truncated having a flat side in comparison to the configured [sic] shown in figure 15. The flat side allows the implant to be more closely nested.” Without acquiescing in this assertion, Applicant has amended the claims for the purpose of drawing

out distinctions between the claimed invention and the subject matter described in Grosse, thereby expediting the allowance of this case. These amendments are made without prejudice to Applicant's right to further pursue patent protection for the subject matter recited in the prior claims at a later time.

Specifically, upon entry of the present amendments, claims 15 and 16 are cancelled, and each of the remaining rejected claims recites an implant system for promoting fusion bone growth wherein a first end piece of a first load bearing member has "a truncated surface that defines a cutout region" and a first end piece of a second load bearing member "is nested within said cutout region." The Examiner states in the outstanding Action indicate that, "the implants as shown in figures 4-5 [of Grosse] are interpreted as being 'nested' together in the same vertebrae space." The Examiner's statement implies that he is interpreting the term "nested" itself to mean "positioned together in the same vertebrae space." In reply, Applicant submits that this is not a proper interpretation of the term "nested" in the pending claims. Rather, the term "nested" refers to an orientation whereby a portion of an end piece of a second load bearing member resides at a location where a portion of an end piece of a first load bearing member would reside were it not for the first end piece "having a truncated surface that defines a cutout region" as recited in the subject claims, as amended. Applicant submits that the present amendment helps clarify the meaning of the term "nested" in this regard, and that the Grosse reference cannot properly be found to anticipate claims 1-2, 10 or 57-58, as amended because it does not

disclose any device in which any element is nested with any other element as that term is properly interpreted in view of the present specification.

In view of the above, Applicant respectfully submits that claims 1-2, 10 and 57-58 are allowable over the cited Grosse reference and respectfully requests that the rejection under 35 U.S.C. §102(b) be withdrawn.

In the outstanding Office Action, claims 1-2, 9-11, 13, 15, 30, 32-33, 36-38, 42 and 57-60 are rejected under 35 U.S.C. §102(b), as being anticipated by Brosnahan, III (5,645,598). In traversal of this rejection, Applicant submits that the pending claims, as amended, are not anticipated by the '598 patent at least because the '598 patent does not disclose a device that includes a "central element" extending between "opposite end pieces" with dimensions as recited in the identified claims.

Applicant would first note that of the claims rejected under §102(b) as being anticipated by the '598 patent, only claims 1, 30, 32 and 57 are independent. Each of these independent claims recites a central element configuration and dimensional limitations thereof that are not disclosed in the '598 patent. In particular, claim 1 recites:

said central element being sized smaller relative to said opposite end pieces to define a pocket between said central element and the adjacent vertebrae when the adjacent vertebrae are supported by said opposite end pieces, said pocket configured to contain an osteogenic material disposed about said central element and in intimate contact with the adjacent vertebrae when the vertebrae are supported by said opposite end pieces

Claim 30 recites:

said central element being sized relative to said opposite end pieces to define a pocket between said central element and the adjacent vertebrae when the adjacent vertebrae are supported by said opposite end pieces,

said pocket configured to contain an osteogenic material disposed about said central element and in intimate contact with the adjacent vertebrae when the vertebrae are supported by said opposite end pieces

Claim 32 recites:

said central element of said first fusion device having an outer diameter; wherein said first and second end piece of said first fusion device each have an outer diameter that is greater than said outer diameter of said central element of said first fusion device to minimize stress shielding along said central element of said first fusion device

Claim 57 recites:

the central element being sized smaller relative to said opposite end pieces to define a pocket between said central element and the adjacent vertebrae when the adjacent vertebrae are supported by said opposite end pieces, . said pocket configured to contain an osteogenic material disposed about said central element and in intimate contact with the adjacent vertebrae when the vertebrae are supported by said opposite end pieces

Applicant submits that the '598 patent does not disclose any device that includes a central element having dimensions that meet the above-identified limitations of any of claims 1, 30, 32 or 57, as amended. Therefore, these claims cannot properly be held to be anticipated over the '598 patent.

The remaining claims rejected in the Action as being anticipated by the '598 patent are dependant claims that depend, directly or indirectly, from one of claims 1, 30, 32 or 57. Applicant submits that the dependent claims are in condition for allowance for at least these same reasons and for other reasons.

In view of the above, Applicant respectfully submits that claims 1-2, 9-11, 13, 15, 30, 32-33, 36-38, 42 and 57-60 are allowable over the '598 patent and respectfully requests that the rejection thereof under 35 U.S.C. §102(b) be withdrawn.

### **Remarks Regarding Rejection of Claims Under 35 U.S.C. §103(a)**

In the outstanding Office Action, claims 1-2, 9-11, 13, 15, 30, 32, 33, 36-38, 42, 44, 45 and 55-63 are rejected under 35 U.S.C. §103(a), as being unpatentable over Ulrich (DE 19630256) in view of Michelson (6,123,705). Applicant traverses this rejection and submits that the rejection is improper at least because either (1) the presently claimed invention is not obvious over the cited combination, or (2) the primary reference relied upon by the Examiner (the Ulrich reference) does not qualify as prior art due to the present inventor's prior invention that antedates the Ulrich reference.

#### **Showing Prior Invention**

A showing of prior invention (i.e., invention prior to a given "target date" such as the effective date of a reference) is made by establishing a reduction to practice prior to the target date or by establishing conception of the invention prior to the target date coupled with due diligence from prior to said target date to a subsequent reduction to practice or to the filing of a patent application (which is considered to be a constructive reduction to practice of the invention(s) disclosed therein). (See e.g., 37 C.F.R. §1.131 and 35 U.S.C. §102(g)). In view of these principles, a U.S. Patent on its fact is sufficient to establish a date of invention at least as early as its earliest effective filing date for all inventions that are disclosed therein because the filing of the application is a constructive reduction to practice.

Under 37 C.F.R. §1.131 ("Rule 131"), the prior art effect of a reference with respect to a rejected patent claim can be nullified by establishing that the claimed invention was made prior to the effective date of the reference. In addition, under certain circumstances the

prior art effect of a reference with respect to a rejected patent claim can be nullified even without evidence that the whole invention recited in the claim was made prior to the effective date of the reference. In such circumstances, to nullify the prior art effect of a reference it is sufficient to show that the inventor had reduced to practice something less than the whole invention, but at least the subject matter of the reference that is relied upon by the Examiner to make the rejection.

One scenario in which the Patent Office acknowledges a reference can be removed by a showing of prior invention of less than all of the subject matter recited in a claim is where (1) the inventor himself, prior to the effective date of the reference, invented the subject matter disclosed in the reference and relied upon to make a rejection, and (2) the claimed invention would be obvious to a person of ordinary skill in the art in view of the evidence of Applicant's prior invention. In re Stryker, 435 F.2d 1340, 168 USPQ 372 (CCPA 1971). This principle (referred to herein as the "Stryker principle") is also discussed in Section 715.02 of the Manual of Patent Examining Procedure in the context of Rule 131 swear behind declarations. This section states the following:

Even if applicant's 37 CFR 1.131 affidavit is not fully commensurate with the rejected claim, the applicant can still overcome the rejection by showing that the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of applicant's 37 CFR 1.131 evidence, prior to the effective date of the reference(s) or the activity. Such evidence is sufficient because applicant's possession of what is shown carries with it possession of variations and adaptations which would have been obvious, at the same time, to one of ordinary skill in the art.

#### Prior Invention of Applicant William F. McKay

In the present case, Applicant submits that the inventor's own prior patent, U.S. Patent No. 6,146,420 (hereafter "the '420 patent"), filed December 10, 1997, discloses at least the subject matter as that from the Ulrich reference upon which the Examiner relies in making the present rejection. In making the present rejection, the Examiner identifies the pertinent teaching of the Ulrich reference as follows: "Ulrich teaches a first cylindrical fusion device being dumbbell shaped including a [sic] opposing end pieces 17, 18 and a central element 19 connecting said opposing end pieces." Applicant submits that the inventor's own '420 patent discloses at least this same subject matter (see, e.g., Figures 1, 3, 4, 9, 12 and 16 of the '420 patent and associated descriptions in the specification). Assuming this the date of invention for all that is disclosed in the '420 patent to be at least as early as December 10, 1997 (without prejudice to Applicant's right to establish an earlier date of invention should he wish to do so at a later time), the date of invention of the subject matter disclosed in the '420 patent is prior to the effective date of the Ulrich reference. Thus, the present inventor had himself invented, before the effective date of the Ulrich reference, the subject matter upon which the Examiner relies in making the present rejection.

Because the '420 patent is included in the official records of the U.S. Patent Office, it is on its face sufficient to establish that the present inventor reduced to practice (constructively) the inventions described and claimed therein at least as early as its filing date, December 10, 1997. The existence of the '420 patent therefore has the same effect as would a Declaration Under Rule 131 with respect to providing evidence of Applicant's invention. Thus, it is believed that a separate Declaration Under Rule 131 is not needed in



the present case to establish prior invention due to the presence of the necessary facts in an issued U.S. patent.

#### The Obviousness Element

As stated above, one factor that is considered by the Patent Office to be necessary to remove a reference under the Stryker principle is a showing that the claimed invention would be obvious to a person of ordinary skill in the art in view of the evidence of Applicant's prior invention. Thus, whether or not the presently claimed invention would have been obvious to a person of ordinary skill in the art at the time the invention was made over the subject matter of Applicant's prior invention, taken together with all other information available to the skilled artisan at the time of the invention, bears on the present analysis.

It is important to recognize that the question of the obviousness or nonobviousness of the claimed invention over the Ulrich reference, which bears on the analysis of the Stryker principle, IS THE SAME AS the question of the obviousness or nonobviousness of the claimed invention under Section 103 of the Patent Statute. Logic dictates that there are only two (2) possibilities: either the presently claimed invention IS obvious over the disclosure of the Ulrich reference (and thus Applicant's own prior invention) in view of all other information available to the skilled artisan at the time of the invention, or the presently claimed invention IS NOT obvious over the disclosure of the Ulrich reference (and thus Applicant's own prior invention) in view of all other information available to the skilled artisan at the time of the invention.

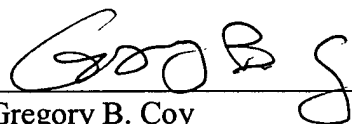
If the claimed invention IS NOT obvious over the disclosure of Ulrich in view of all other information available to the skilled artisan at the time of the invention, the rejection of the subject claims under Section 103 in the outstanding Office Action must be withdrawn. On the other hand, if the presently claimed invention IS obvious over the disclosure of Ulrich (and thus Applicant's own prior invention) in view of all other information available to the skilled artisan at the time of the invention, the Ulrich reference cannot properly be cited as prior art due to the Applicant's prior invention, as per the Stryker principle.

In view of the above, Applicant respectfully submits that claims 1-2, 9-11, 13, 15, 30, 32, 33, 36-38, 42, 44, 45 and 55-63 are allowable over the references of record and respectfully requests that the rejection under 35 U.S.C. §103 be withdrawn.

**Closing**

Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, as amended and including claims 1, 2, 9-13, 30, 32, 33, 36-38, 42, 44-46, 55-63 and 66-67 pending and under consideration, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

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